UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., Plaintiff, v. RANBAXY LABORATORIES LTD., RANBAXY INC., AND RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-8597-TPG C.A. No. 13-cv-4343-TPG
ENDO PHARMACEUTICALS INC., Plaintiff, v. ROXANE LABORATORIES, INC., Defendant.	C.A. No. 13-cv-3288-TPG

ENDO'S OPPOSITION TO RANBAXY AND ROXANE'S MOTION *IN LIMINE* TO EXCLUDE ALLEGEDLY UNQUALIFIED TESTIMONY OF REZA FASSIHI, PH.D.

Plaintiff, Endo Pharmaceuticals Inc. ("Endo"), through its attorneys, submits this memorandum together with the accompanying Declaration of Dr. Reza Fassihi and Declaration of Brian M. Goldberg in support of Endo's opposition to Defendants' Motion *In Limine* To Exclude Unqualified Testimony of Reza Fassihi, Ph.D. (the "Motion *In Limine*").

I. INTRODUCTION

Dr. Fassihi is a Professor of Biopharmaceutics and Industrial Pharmacy at The Temple University School of Pharmacy with over 30 years of experience in pharmaceutical development. In his role as a pharmacist and professor of pharmacy he regularly reads, interprets and teaches about information from product labels and package inserts. Physicians regularly seek Dr. Fassihi's advice in making decisions on how to prescribe prescription medication. Despite Dr. Fassihi's abundance of experience, Defendants argue that because he is not a medical doctor he is not qualified to testify as an expert on issues regarding the container label and package insert that provides instructions to prescribers, pharmacists, and patients on how to use Defendants' products. Additionally, Defendants argue that since Dr. Fassihi relied on the opinions of Dr. Edward Ross, a medical doctor also serving as an expert for Endo, his opinions on the long-felt need for Opana ER ® are duplicative. More specifically, the Defendants' assert that because Dr. Fassihi is not a physician he should be precluded from offering opinions on:

- "issues such as how a physician would prescribe Roxane's and Ranbaxy's respective ANDA products…"
- "how a physician instructs a patient to take the product with food…."
- "how a patient could perform the required steps in the asserted method claims calling for 'providing' a solid oral dosage form and 'administering' a single dose."
- "a purported-long-felt need in the medical community…"

(Motion *In Limine* at 3-4). Defendants' motion should be denied because their arguments ignore the standard of admissibility of expert testimony under Fed. R. Evid. 702 and ignore Dr. Fassihi's abundant and relevant qualifications.

II. LEGAL STANDARD

Federal Rule of Evidence 702 provides a liberal standard of admissibility for expert opinions. *Emig v. Electrolux Home Products*, Case No. 06-cv-4791 (KMK), 2008 WL 4200988 (S.D.N.Y Sept. 11, 2008); *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp*., Case No. 04 Civ. 7369 (LTS), 2006 WL 2128785 (S.D.N.Y. Jul. 2006). Before permitting expert testimony the district court must determine 1) whether the witness is qualified to be an expert, 2) whether the opinion is based upon reliable data and methodology; and 3) whether the expert's testimony on a particular issue will assist the trier of fact. *Emig*, 2008 WL 4200988 at *3; *see In re Omeprazole Patent Litigation*, 490 F.Supp.2d 381, 400-01 (S.D.N.Y. 2007).

Courts look at the totality of the witness's qualifications. *See Emig*, 2008 WL 4200988 at *4; *In re Zyprexa Products Liability Litigation*, 489 F.Supp.2d 230, 282 (E.D.N.Y. 2007); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 741 (3d Cir. 1994). Experts are permitted to testify concerning any topics in the general field of their expertise: "If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." *In re Zyprexa*, 489 F.3d at 282; *see McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995); *Stagly v. Delta Air Lines, Inc.*, 117 F.3d 76, 80 (2d Cir. 1997).

III. ARGUMENT

Dr. Fassihi is more than qualified to testify about all of the topics addressed in his expert report including the impact of the container label and package insert on prescribers and patients

and the long-felt need within the medical community for Opana ER ®. Dr. Fassihi is currently a professor of Biopharmaceutics and Industrial Pharmacy at Temple University School of Pharmacy in Philadelphia, Pennsylvania. Dr. Fassihi's teaching and research include the disciplines of pharmacology, biopharmaceutics, and pharmaceutical dosage form development. He has authored or coauthored more than 130 peer-reviewed professional articles. Not surprisingly, Defendants omit important portions of Dr. Fassihi's expert reports explaining his relevant professional experience. Endo refers the Court to Dr. Fassihi's CV (Fassihi Decl. Ex.A) and Section III "Expert Qualifications" of Dr. Fassihi's Opening Expert Reports for a full statement of his qualifications and professional experience. (Goldberg Decl. Exs. A-C). Some of the key qualifications that Defendants notably omit from the excerpts provided in the Sudentas Declaration include the following:

- "I have been teaching and conducting research for the last 30 years at both the undergraduate and graduate levels, teaching courses in applied biopharmaceutics, pharmaceutical dosage forms, modified release products, and pharmaceutical manufacturing. I have taught and trained thousands of Doctor of Pharmacy graduate students from the Temple School of Pharmacy. I have also supervised 26 Ph.D. students and more than 10 graduate students for masters and a number of postdoctoral fellows and visiting scientists working in the area of drug delivery systems."

  (Goldberg Decl. Ex. A; 10/30/2014 Dr. Fassihi Opening Infringement Report (Roxane) ¶12).

- "My research includes the disciplines of pharmacology, biopharmaceutics, and pharmaceutical dosage form development. Pharmacology is the understanding of a drug molecule and its effect on the body, cells, and tissues. Biopharmaceutics, when combined with industrial pharmacy, encompasses drug delivery system design in relation to drug molecule and kinetics of release (both *in vitro* and *in vivo*), absorption kinetics and bioavailability in terms of rate, extend, and duration. In effect, biopharmaceutics brings together the active pharmaceutical ingredient and its physiochemical properties, dosage form, bioabsorption, pharmacokinetics as they related to drug delivery, and finally optimization of therapeutic outcome through rate kinetics. Accordingly, my research involves the study and evaluation of active pharmaceutical ingredients, pharmaceutical compositions, and delivery systems employed for delivering the pharmaceutically

active ingredient to a particular site in a patient where the drug is released or needed. This research encompasses all aspects of pharmaceutical compositions: from the initial concepts or pre-formulation work through industrial scale production of the final pharmaceutical composition. This research also includes the study and evaluation of the manner in which the drug and pharmaceutical composition behave or react in the patient."

(Goldberg Decl. Ex. A; 10/30/2014 Dr. Fassihi Opening Infringement Report (Roxane) ¶ 13).

- "At least twenty pharmaceutical companies have retained me as a consultant, such as AstraZeneca, GlaxoSmithKline, Pfizer, McNeil, Bristol Meyers, Schering Plough, Wyeth, Scolor, Eurand, Colorcon Inc., and Delysis. My work with these companies includes providing expertise in areas such as biopharmaceutics (bioavailability and bioequivalency requirements), formulation development issues, trends in modified release pharmaceutical compositions, and factors involved in the development of pharmaceutical compositions."

  (Goldberg Decl. Ex. A; 10/30/2014 Dr. Fassihi Opening Infringement Report (Roxane) ¶18).

Dr. Fassihi has prepared a declaration to more fully set forth his qualifications with respect to the issues raised by Defendants. ("Fassihi Decl." submitted herewith). It is a principal responsibility of pharmacists to ensure that patients receive a safe and effective dose of drugs prescribed by doctors. (Fassihi Decl. ¶ 5). Dr. Fassihi is a pharmacist by training and has been teaching pharmacy and other pharmaceutical sciences to graduate students, pharmacists, and medical students, and has been conducting research in those areas for the past 30 years. (Fassihi Decl. ¶ 2). As a professor of Biopharmaceutics and Industrial Pharmacy at Temple University School of Pharmacy, Dr. Fassihi teaches his students to serve as partners to physicians, nurses, and other healthcare professionals. (Fassihi Decl. ¶ 7). This includes working with health care professionals to ensure that patients receive appropriate dosing of prescription drugs like Opana ® ER. (Fassihi Decl. ¶ 7). Pharmacists consult with and advise patients and physicians, as well as other health care professionals regarding the proper dosage and administration of medications, including the selection of appropriate dosage forms, strengths of drugs, and usages of

medications. (Fassihi Decl. ¶ 3). It is common for pharmacists to explain to patients prescribing instructions, including those described in the package inserts and medication guides provided with prescription drugs. (Fassihi Decl. ¶ 5).

In Dr. Fassihi's role as a professor in biopharmaceutics and industrial pharmacy and as a consultant to various pharmaceutical companies regarding pharmaceutical drug development, he reviews product labels, package inserts, and information in the *Physician's Desk Reference*[1] (commonly referred to as the "PDR") on a regular basis. (Fassihi Decl. ¶ 4). As such, he is intimately familiar with the contents of product labels, and package inserts and is proficient at reading and interpreting their contents. (Fassihi Decl. ¶ 4). Dr. Fassihi's role as a pharmaceutical scientist involves advising and assisting health care professionals, including physicians, to ensure that patients receive the proper dosage of a drug. (Fassihi Decl. ¶ 5). Physicians at Temple University Hospital and other hospitals in the Philadelphia area contact Dr. Fassihi on a regular basis to seek his advice on selection of different dosage forms and their strengths, as well as usages of the medications for their patients. (Fassihi Decl. ¶ 6). He personally has contacted physicians where he thought a prescription would not provide an effective dosage form for a patient in light of the drug's prescribing information. (Fassihi Decl. ¶ 5). Dr. Fassihi even lectures medical students on pharmaceutical dosage forms, including issues related to pharmacokinetics and pharmacodynamics of drugs. (Fassihi Decl. ¶ 7).

Dr. Fassihi's educational and professional experience plainly shows that Defendants' conclusory statement that "[p]harmaceutics experts such as Fassihi do not concern themselves with product labels and how, if at all, to communicate their contents, suggestions, or instruction to anyone" is baseless and incorrect. Package inserts and product labels instruct medical

[1] The PDR is a compilation of manufacturers' prescribing information from the package inserts of prescription drugs. (Fassihi Decl. ¶ 4).

professionals, pharmacists, and patients on how to use the product. In addition, not all portions of the package insert that Dr. Fassihi relies on in forming his infringement opinion are drafted toward medical professionals. For instance, Dr. Fassihi relies on the Medication Guide in his infringement reports (*see, e.g.*, Goldberg Decl. Ex. A, 10/30/2014 Dr. Fassihi Opening Infringement Report (Roxane) ¶ 91; Goldberg Decl. Ex. B, 10/30/2014 Dr. Fassihi Opening Infringement Report (Ranbaxy Non-CRF) ¶ 93; Goldberg Decl. Ex. C, 10/30/2014 (Ranbaxy CRF) ¶ 93), which is written for a lay audience. (*See An Introduction to the Improved FDA Prescription Drug Labeling – Transcript*, http://www.fda.gov/Training/ForHealthProfessionals/ucm090801.htm ("In contrast, FDA-approved patient information, which includes patient package inserts and medication guides, is specifically written for a lay audience and is intended to be read by patients.")). Defendants cannot seriously claim that a person with Dr. Fassihi's professional and educational background is not qualified to give opinions on how a drug will be prescribed based on the container label and package insert that provides prescription instructions.

Moreover, Dr. Fassihi is qualified to testify as to the long-felt need for Opana ER®. Defendants only cite two paragraphs of Dr. Fassihi's opinion on long-felt need to which they apparently take issue. Defendants claim that not only is Dr. Fassihi's testimony unreliable because he is not a medical doctor, but it also is cumulative since Dr. Fassihi relies in part on the opinions of Dr. Ross, a medical doctor serving as an expert for Endo in this case. Dr. Fassihi is an expert on modified release dosage forms. As such, he is fully capable of understanding the use and need for extended release opioids for the treatment of chronic pain along with the efforts of scientists in the field in trying to overcome the challenges in developing them.

In addition, Dr. Fassihi's reference to the opinions of Dr. Ross serves to corroborate a portion of his opinion on long-felt need, not duplicate it. An expert's testimony that adopts the contents of another expert is admissible under Fed. R. Evid. 702. *See, e.g., Eli Lilly Co. v. Actavis Elizabeth LLC*, Civ. No. 07-cv-3770 (DMC), 2010 WL 1931233, *3 (D.N.J. May 7, 2010) ("Dr. Johnson's testimony, in conjunction with the expert report of Dr. Shukla (the contents of which have been adopted by Dr. Johnson), is admissible under Fed. R. Evid. 702.") Dr. Fassihi only incorporates Dr. Ross' opinions in one paragraph of his section addressing the long-felt need for Opana ER®. (Sudentas Decl. Ex. 6; 12/11/2014 Dr. Fassihi Rebuttal Expert Report, ¶ 345). In addition to incorporating the opinions of Dr. Ross he also discusses a variety of other factors, such as the properties of oxymorphone that precluded development of a controlled release dosage form. Accordingly, Dr. Fassihi's testimony that there was a long-felt need for Opana ER ® is not cumulative of Dr. Ross's testimony, and the Court should permit Dr. Fassihi to testify on the topic.

IV. CONCLUSION

For all the reasons set forth above, the Court should permit Dr. Fassihi to testify on all the topics covered in his expert reports.

DATED: March 16, 2015

By: */s/ Brian M. Goldberg*

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CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2015, I caused the foregoing **ENDO PHARMACEUTICALS INC.'S OPPOSITION TO DEFENDANTS MOTION *IN LIMINE* TO EXCLUDE UNQUALIFIED TESTIMONY OF REZA FASSIHI, PH.D,** together with supporting memorandum of law, declaration of Brian M. Goldberg, and declaration of Dr. Reza Fassihi, Ph.D. and all Exhibits to be served on counsel for Defendants as follows:

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